PCA UPDATE
ONCOLOGY DRUG ADMINISTRATION
February, 1993

The Problem -- Oncology Drug Administration

Within the last six months, the Board's PCA Unit has received several major incident reports involving adverse patient outcomes, including two deaths, related to the oncology drug, Platinol (Cisplatin). These outcomes resulted from the administration of excessive dosages of this drug which, in turn, was caused by calculation errors. For example, in three cases, the patients received, in one day, the doses they were intended to have received over a multiple-day time period. Unfortunately, the errors were not detected by the hospitals before the dosages were given, because either the check system in place failed or there was no system to guard against this type of error.

Factors Contributing to the Problem

The PCA Unit and Board members were quite alarmed by these reports. Over several weeks, staff gathered information on the causes of the problem and possible solutions. A number of people were contacted for their expertise and advice, including hospital risk managers, oncologists, and investigators and epidemiologists from the Massachusetts Department of Public Health, Food and Drug Division, and the U.S. Food and Drug Administration.

The experts agreed that this type of medication error was not unique to Cisplatin, but, rather, was associated with oncology drugs in general. Many reasons were given for this: the highly specialized nature of these drugs; the fact that patients' drug protocols are constantly changing; the high degree of toxicity associated with oncology drugs and the often high risk tolerance for cancer patients; the shift of treating cancer patients from an in- to an out-patient basis; and the lack of appropriate back-up and checking systems in facilities.

Other types of problems associated with oncology drugs were cited, including medication errors related to drugs with similar-sounding names (e.g., Cisplatin and Carboplatin) and mistakes resulting from medication orders given over the phone. Unfortunately, the experts also agreed that these problems occur "...more than you know."

A Possible Risk Management Solution

Although no one solution was proposed, a common principle was repeated by many of those contacted. Facilities with active hematology/oncology departments should have double, or optimally, triple check drug administration systems which would include the participation of oncologists, nurses, and pharmacists. For these systems to be effective, they must include checking the medication(s) ordered against the patient's particular drug protocol. If the patient is not on a protocol, then some kind of chemotherapy flow sheet should be formulated which would include, among other things, the patient's height, weight, body surface area, oncology drug(s) treatment plan, all other medication he/she is taking, and pertinent lab results.

Again, the critical element to the system's effectiveness is that the medication(s) ordered is(are) triple-checked against the patient's protocol and/or planned drug regimen, not just against the "usual" or "recommended" dosages. As one risk manager pointed out, 150 mg./m2 of Cisplatin, although possibly appropriate for a patient on the tenth day of his/her protocol or regimen, could be lethal for a patient just beginning his/her treatment plan.

System Implementation

One of the hospitals which was contacted adopted this triple check system five years ago, following the death of a patient who had received an excessive dose of an oncology drug. This particular hospital enters all of its cancer patients' protocols on the pharmacy computer to facilitate the check system. According to the hospital's risk manager, this did not involve much cost or effort. Further, the hospital reports that, since the adoption of the system, there have been no similar problems with oncology drugs.

Conclusion/Recommendation

The Board believes that had the system described above been in place or enforced at the hospitals where the reported major incidents occurred, the patient deaths and other serious outcomes could have been avoided.

This information is being shared with hospitals in order to increase awareness of these potential patient risks and to help prevent future adverse occurrences. The Board suggests that PCA Coordinators and/or other appropriate personnel examine the facility's current system for administering oncology drugs and, if it is unlikely to detect miscalculation errors or to prevent other problems associated with the administration of oncology drugs, to consider adopting the triple check system (or variation thereof) described in this report.

If your own facility has experience in dealing with this issue and would like to share a successful risk management solution with other hospitals, please contact the PCA Unit and we will include it in a follow-up mailing.